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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
MARI, S.	
ART UNIT	**PAPER NUMBER**
1301	23

DATE MAILED: 11/13/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8-5-96.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 61-64, 74-76, 79, 80 and 83-93 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 61-64, 74-76, 79, 80 and 83-93 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification as originally filed does not provide support for the invention as is now claimed.

Although the specification supports forming a biaxially oriented outer layer, the original specification fails to support the limitation of biaxially orienting the tensile layer and the inner bonding layer as set forth in claim 83. For example, where does the original specification support melting a biaxially oriented inner layer so as to bond the balloon to the catheter? Another example, where is the support for biaxially orienting a ethylene propylene inner layer or a polysiloxane inner layer as set forth in claim 75?

2) Claims 74-76, 79, 83-85 and 90-93 (Claim 83 and its dependent claims) are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

3) The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Wang et al as a primary reference

4) Claims 61-64, 80, 86-89 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy, Patel and Nunez[1].

Wang et al, directed to the catheter art, discloses coextruding a tube wherein the coextruded tube has an outer layer

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[1]Wang et al (US Patent 5,195,969 filed 4-26-91) is prior art under 35 USC 102(e) since none of the claims in this application are fully supported by the disclosure of the 07/411,649 (none of the claims in this application are entitled to the benefit of the filing date 9-25-89 of 07/411,649). See MPEP 201.11. For example, claim 80 is not fully supported by 07/411,649 since 07/411,649 fails to support the step of adhesively bonding using a separate adhesive. Another example: claim 62 is not fully supported by 07/411,649 since 07/411,649 fails to support using PEEK as the outer layer. Another example: claim 83 is not fully supported by 07/411,649 since 07/411,649 fails to support the limitation of the inner bonding layer being one which adheres readily to the outer surface of a catheter body using a method selected from the group consisting of melt bonding and glue adhesion or a combination thereof as set forth in step (a) of claim 83.

and an inner layer and forming the tube into a balloon such that the outer layer is biaxially oriented and the inner layer can be heat bonded to a catheter. The outer layer may be made from material such as polyethylene terephthalate or polyamide (nylon) and the inner layer may be made from material such as polyethylene. At columns 5 and 6, Wang et al discloses heating the tube, drawing it and expanding it, but does not specifically disclose heating and drawing the balloon so that it exhibits a burst strength greater than seven atmospheres.

Levy, also directed to the catheter art, teaches heating a polyethylene terephthalate tube, drawing the tube and radially expanding the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm).

As to claim 80, it would have been obvious to heat the coextruded tube of Wang et al, draw the coextruded tube and radially expand the coextruded tube in a blow molding fixture so that the outer layer is biaxially oriented and the balloon has a burst pressure of at least 200 psi (13.6 atm) since (a) Wang et al and Levy both disclose forming a balloon for a catheter from a tube and (b) Levy suggests that a biaxially oriented balloon, which was made by heating a tube, drawing the tube and radially expanding the tube and which has a burst pressure of at least 200 psi (13.6 atm), is especially useful in medical dilation procedures.

As to claim 80, the limitation of adhesively bonding using a separate adhesive as set forth in claim 80 would have been obvious in view of (a) Wang et al's teaching to attach the balloon to the catheter tube, (b) Patel's teaching to attach a balloon to a catheter tube by using an adhesive or by heat sealing and (c) Nunez which shows that it is well known in the catheter art to attach a balloon to a catheter tube using a separate adhesive.

As to claims 61-64, 86 and 87, the limitation of the material of the outer layer and the material of the inner layer as set forth in claims 61-64, 86 and 87 would have been obvious in view of (a) Wang et al's teaching to use material such as polyethylene terephthalate or polyamide (nylon) for the outer layer and (b) Wang's teaching to use material such as polyethylene for the inner layer.

As to claim 88, the limitation of the outer layer as set forth in claim 88 would have been obvious since (a) Wang et al teaches using polyamide such as nylon for the material of the outer layer and (b) each of the nylon materials listed in claim 88 are taken as well known / conventional types of polyamide (nylon) material.

As to claim 89, the limitation of the inner layer as set forth in claim 89 would have been obvious since (a) Wang et al teaches using a thermoplastic material for the inner layer and

(b) a low melting polyester is taken as a well known / conventional type of thermoplastic material.

5) Claims 84 and 91 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy, Patel and Nunez as applied above and further in view of Merrill and Lambert.

Wang et al does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claims 84 and 91, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Wang et al teaches bonding the balloon which comprises the outer layer to a catheter tube to form a catheter and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

6) Claims 74-76, 79, 83, 85, 90, 92, 93 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy, Merrill and Lambert.

Wang et al is discussed above.

As to claim 83, it would have been obvious to heat the coextruded tube of Wang et al, draw the coextruded tube and radially expand the coextruded tube in a blow molding fixture so that the outer layer is biaxially oriented and the balloon has a burst pressure of at least 200 psi (13.6 atm) since (a) Wang et al and Levy both disclose forming a balloon for a catheter from a tube and (b) Levy suggests that a biaxially oriented balloon, which was made by heating a tube, drawing the tube and radially expanding the tube and which has a burst pressure of at least 200 psi (13.6 atm), is especially useful in medical dilation procedures.

As to claim 83, the limitation of biaxially orienting both layers would have been obvious in view of Wang et al's teaching to form a balloon from a tubular extrusion of at least two layers and Levy's teaching to biaxially orient a tubular extrusion.

As to claim 83, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Wang et al teaches bonding the balloon which comprises the outer layer to a catheter

tube to form a catheter and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

As to claims 83 and 85, the limitation of bonding by melt bonding would have been obvious in view of Wang et al's teaching to attach the balloon to the catheter by heat bonding.

As to claim 74, the limitation of claim 74 would have been obvious in view of Merrill teaching to use N-vinyl pyrrolidone as a hydrophilic material.

As to claims 75, 76 and 79, the limitation of the material of the outer layer and the material of the inner layers as set forth in claims 75, 76 and 79 would have been obvious in view of (a) Wang et al's teaching to use material such as polyethylene terephthalate or polyamide (nylon) for the outer layer and (b) Wang's teaching to use material such as polyethylene for the inner layer.

As to claims 90, 92 and 93, the limitation of the outer layer as set forth in claims 90, 92 and 93 would have been obvious since (a) Wang et al teaches using polyamide such as nylon for the material of the outer layer and (b) each of the nylon materials listed in claim 90, 92, 93 are taken as well known / conventional types of polyamide (nylon) material.

Levy as a primary reference

7) Claims 61-64 and 80 are rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Levy in view of Japan '463 (JA 58-188463), "Coextruded composite film" by Parker, Patel and either Nunez or Dyke; the combination taken alone or further in view of Japan '353 (JA 53-45353).

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the balloon catheter comprising the balloon by means of conventional techniques.

Japan '463 shows a balloon secured at each end to a catheter tube wherein the balloon comprises two layers 13 and 14. See abstract, figures. During an oral translation of Japan '463 by a PTO translator, the following information was obtained: Japan '463 discloses that layer 14 is a gas penetration layer which was formed by coating over a soft plastic film 13.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube with air to stretch the tube to a desired thickness. Parker

teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure. Parker et al teaches that by providing the second layer a "good sealing film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exits in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of the "property advantages offered by specially tailored coextruded composite films"

As to claim 80, it would have been obvious to:

(i) coextrude two layers so as to form a two layer tubing; and

(ii) use the two layer tubing in the Levy process which as noted above includes steps of heating the tube, drawing the tube and radially expanding the tube in a blow molding fixture to form the balloon SINCE:

(a) Levy teaches extruding plastic material to form a tubing which is to be used to form a balloon;

(b) Japan '463 teaches forming a two layer balloon for the advantage of making the balloon more gas impermeable;

(c) Parker suggests coextruding a low melting point plastic material with a high melting point plastic material in order to form a two layer tube which is virtually free from pinholes; and

(d) the use of coextrusion to form tubing is known per se in the balloon catheter art for the purpose of improving bonding as shown by Patel

AND OPTIONALLY SINCE:

(e) Japan '353 shows the use of coextrusion and biaxial orientation is known per se.

Hence, the prior art as a whole suggests/motivates forming a two layer balloon by the known technique of coextrusion in order to improve the impermeabilty (Japan '463/Parker) and adherabilty (Parker/Patel/Japan '353) of a high burst pressure balloon formed by the process of Levy.

As to the technique used to attach the balloon to the catheter, the following two alternative conclusions are made:

(1) It would have been obvious to one of ordinary skill in the art to attach the balloon to a catheter by using a separate adhesive since (a) Levy suggests fabricating a balloon catheter by a conventional technique which one of ordinary skill in the art would readily understand as including a step of attaching the balloon to a catheter, (b) Patel teaches attaching a balloon to a catheter tube by using an adhesive or by heat sealing and (c)

Nunez which shows that it is well known in the catheter art to attach a balloon to a catheter tube using a separate adhesive.

(2) It would have been obvious to one of ordinary skill in the art to attach the balloon to a catheter by using melt bonding since (a) Levy suggests fabricating a balloon catheter by a conventional technique which one of ordinary skill in the art would readily understand as including a step of attaching the balloon to a catheter, (b) Patel teaches attaching a balloon to a catheter tube by using an adhesive or by heat sealing and (c) Dyke which shows that it is well known in the catheter art to attach a balloon to a catheter tube using melt bonding.

The limitation of the material of the outer layer and the material of the inner layer and the outer layer as set forth in claims 61-64 would have been obvious in view of (a) the above noted suggestion from the secondary references to form a two layer balloon, (b) Levy's al's teaching that the biaxially oriented material of a layer of a balloon may be a polymer such as polyethylene terephthalate and (c) well known polymeric material for a layer of a balloon include polymeric material such as polyvinyl chloride, polyurethane and polyethylene as evidenced by Levy (column 1) and Patel (column 1). With respect to the inner layer being polyethylene, one of ordinary skill in the art would readily recognize from Parker/ Japan '353 that polyethylene would improve the heat sealability of the balloon.

8) Claims 86-89 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463, Parker, Patel and either Nunez or Dyke; the combination taken alone or further in view of Japan '353 as applied above and further in view of Pinchuk et al '244 (US Patent 4,906,244) and Pinchuk et al '466 (US Patent 4,946,466)[2].

As to claims 86, 87 and 88, the limitation of the outer layer as set forth in claims 86, 87, 88 would have been obvious in view of (a) Levy's teaching to use a polymer as the material for the balloon and (b) polyamide (nylon) is a well known / conventional material for a balloon as evidenced by Pinchuk et al '244 and Pinchuk et al '466 and (c) each of the nylon materials listed in claim 88 is taken as well known / conventional types of polyamide (nylon) material.

The limitation of the inner layer as set forth in claim 89 would have been obvious since a low melting polyester is taken as a well known / conventional type of thermoplastic material.

9) Claims 74-76, 79, and 83-85 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463, Parker, Patel and either Nunez or Dyke; the combination taken alone or further in view of Japan '353 as applied above and further in view of Merrill and Lambert.

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[2]It is noted that Pinchuk et al, which was filed 7-24-89 is a CIP of 253069 filed 10-4-88.

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claims 75, 76, 79, 83, 84 and 85, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

As to claim 83, the limitation of biaxially orienting both layers would have been obvious in view of (a) the above noted suggestion from the secondary prior art references to form a balloon from a coextruded tubing and (b) Levy's teaching to biaxially orient a tubular extrusion.

The limitation of claim 74 would have been obvious in view of Merrill's teaching to use N-vinyl pyrrolidone as a hydrophilic material.

10) Claims 90-93 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Japan '463; Parker; Patel; either Nunez or Dyke; Merrill; and Lambert; the combination taken alone or further in view of Japan '353 as applied above and further in view of Pinchuk et al '244 (US Patent 4,906,244) and Pinchuk et al '466 (US Patent 4,946,466).

As to claims 90-93, the limitation of the outer layer as set forth in claims 90-93 would have been obvious in view of (a) Levy's teaching to use a polymer as the material for the balloon and (b) polyamide (nylon) is a well known / conventional material for a balloon as evidenced by Pinchuk et al '244 and Pinchuk et al '466 and (c) each of the nylon materials listed in claims 90-93 are taken as well known / conventional types of polyamide (nylon) material.

11) REMARKS

Applicant's arguments with respect to claims 61-64, 74-76, 79, 80, 83-92 have been considered but are deemed to be moot in view of the new grounds of rejection.

12) No claim is allowed.

13) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D.

Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for Art Unit 1301 is (703) 305-7115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki
November 11, 1996

Steven D. Maki 11-11-96

STEVEN D. MAKI
PRIMARY EXAMINER
GROUP 1300